Coronavirus Disease 2019 (COVID-19) Dual IgG/IgM Rapid Test

Intended Use

The Coronavirus Disease 2019 (COVID-19) IgG/IgM Rapid Test (Whole Blood/Serum/Plasma) is a lateral flow immunoassay for the qualitative detection and differentiation of IgG and IgM of COVID-19 in human whole blood, serum or plasma. This test is intended to be used as an aid in the diagnosis of infection with coronavirus disease.

Negative results do not rule out SARS- CoV-2 infection (the virus that causes COVID-19), particularly in those who have been in contact with the virus.

Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status. Tests should only be performed in conjunction with history and physical exam performed by an independently licensed health care professional. Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains.

Testing procedures must follow Division of Public Health (DPH) guidance. Guidance is available at https://coronavirus.delaware.gov/resources-medical-providers/

Warnings and Precautions

1. Before using the kit, read the instructions carefully and control the reaction time strictly. Inadequate blood supply may deliver inaccurate results. Be sure to deliver adequate blood supply to the sample well. Operational experience has shown that venipuncture may provide a more reliable volume of blood for sampling. The sample well should be saturated to the point of blood pooling. If using the accompanying pipette, ensuring 10-30 µL is delivered to the sample well of the cassette; **2.** Do not allow the product to get wet; **3.** Do not dilute the specimen for testing; **4.** Dispose of kit in accordance with infectious disease protocol; **5.** Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Testing procedures must follow DPH guidance.

Performing the Testing Procedure

1. Follow testing procedures as outlined in the package insert.
2. Obtain blood sample from patient. If performing fingerstick, **f**ill the pipette dropper with the blood specimen to at least the indicated line on the pipette. Holding the dropper vertically, dispense about 10-30 µL of into the sample well, making sure that there are no air bubbles. The sample well should be saturated with blood and cause pooling.
3. If able, venipuncture may provide more reliable blood sampling. Dispense about 10-30 µL of blood into the sample well, making sure that there are no air bubbles. The sample well should be saturated with blood and cause pooling.
4. Then add two drops (about 70-100 µL) of Sample Diluent immediately.
5. Set up timer for 15 minutes. Read and record results at the 14-to-15-minute mark. **It is important not to read results after 15 minutes.**

Limitations of the Test

1. The assay procedure and DPH guidance for implementation and result interpretation must be followed strictly when testing. Failure to follow procedure may give inaccurate results.
2. All positive results should be deemed presumptive positives and appropriate follow-up testing should be immediately sought.
3. Negative results do not rule out SARS- CoV-2 infection, particularly in those who have been in contact with the virus. Testing procedures must follow DPH guidance.

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DELAWARE HEALTH AND SOCIAL SERVICES
Division of Public Health

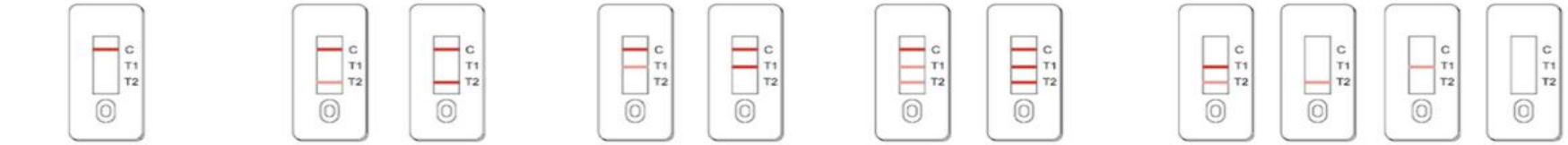
Sample Collection

10-30 µl of blood should saturate the sample well.

2 drops buffer

read result in 15 minutes

Results Interpretation



both IgG IgM Negative

IgM positive,IgG Negative

IgM Negative,IgG positive

both IgG IgM positive

both IgG IgM invalid

If using the pipette bulb, ensure the pipette is filled halfway up the conduit with no bubbles or visible air.

Operational experience has shown that venipuncture may provide a more reliable volume of blood for sampling. The sample well should be saturated to the point of blood pooling.

Failure to deliver adequate blood supply to the sample well may lead to inaccurate results.

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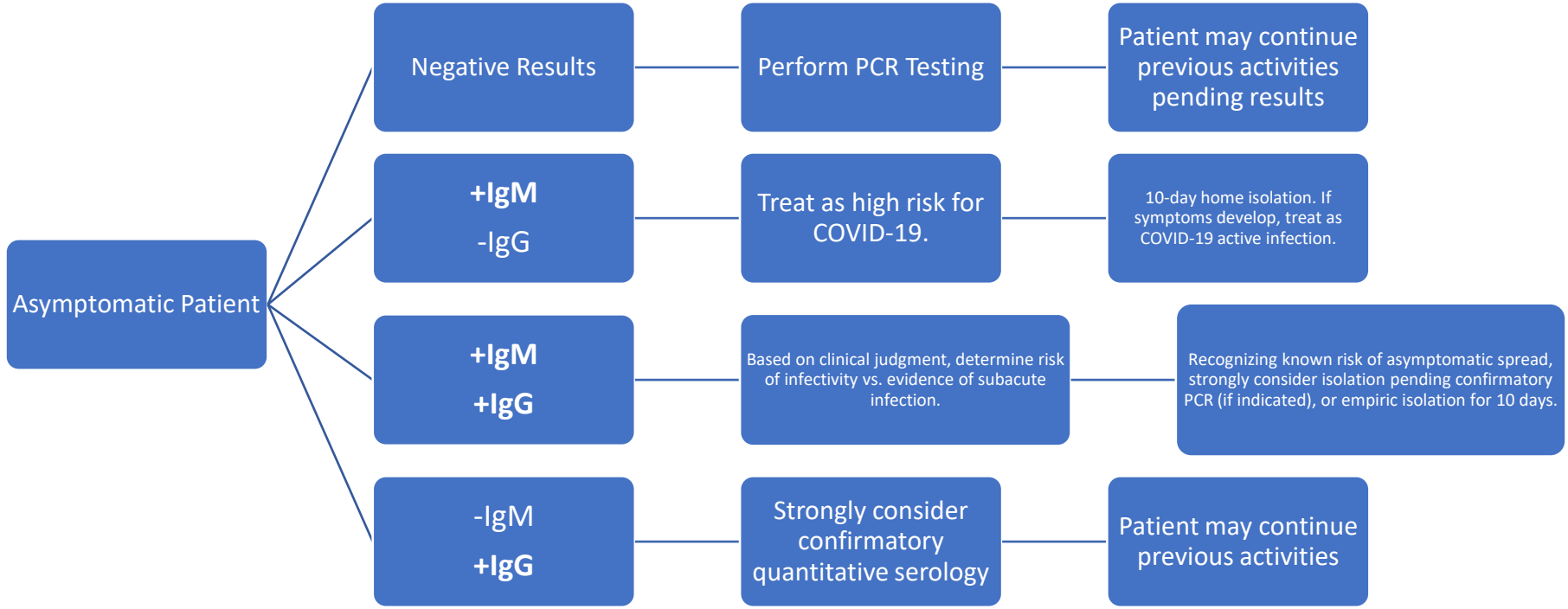

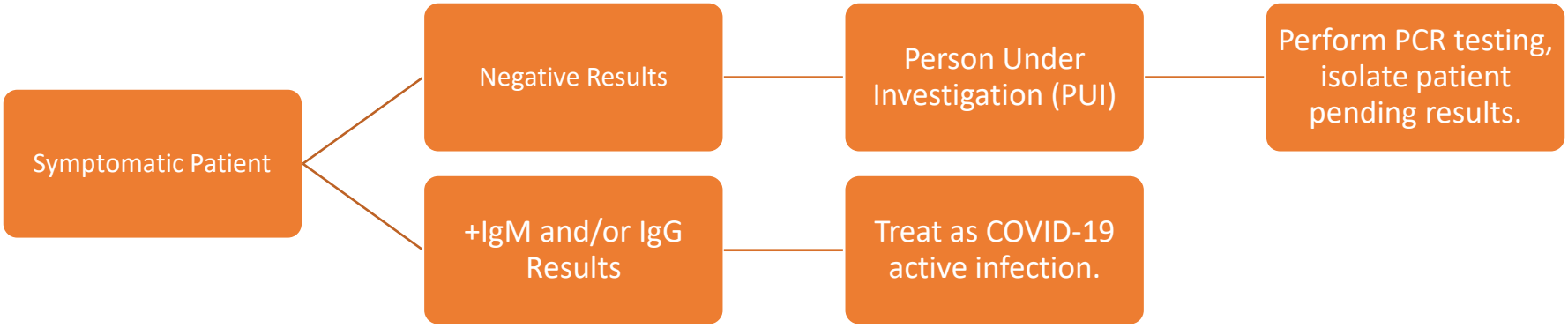

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